

means "that two or more subjects as disclosed are related . . . but are capable of separate manufacture, use, or sale as claimed." (*Id.*)

In order for an application to be properly required to be restricted, there must also be a serious burden on the Examiner (*see* MPEP § 803). Indeed, the MPEP states that if the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions. Because the Office has failed to proffer evidence that both the inventions are independent and distinct as claimed **and** that there is a serious burden on the Examiner, Applicants respectfully traverse the Restriction Requirement and request reconsideration thereof.

Notwithstanding the foregoing, Applicants provisionally elect the "3-untranslated region" of a nucleic acid molecule encoding CD81 of SEQ ID NO:3 (claim 1) and SEQ ID NO:76 (claim 3).

Criteria for Restriction

As set forth in MPEP § 803, there are two criteria for a proper requirement for restriction. First, the inventions must be independent or distinct as claimed.¹ Further, there must also be a serious burden on the Examiner. Applicants respectfully assert that the Office has failed to satisfy the requirements for restriction, failing to provide evidence that searching all the pending claims would constitute a serious burden on the Office.

The Office acknowledges that the Commissioner has partially waived the requirements of 37 CFR § 1.141 and will permit a reasonable number of nucleotide sequences to be claimed in a single application. "Under this policy, up to 10 of independent and distinct nucleotide sequences **will be** examined in a single application. (*see* MPEP §§ 803.04 and 2434)." Moreover, MPEP § 803.04 states that:

nucleotide sequences encoding the same protein are **not** considered to be independent and distinct and will continue to be examined together. In some **exceptional** cases, the complex nature of the claimed material, for example a

¹ As noted above, however, the standard for restriction under 35 U.S.C. §121 is that inventions must be "independent **and** distinct."

protein amino acid reciting three dimensional folds, *may* necessitate that the reasonable number of sequences to be selected be less than 10.

(emphasis added). Further, if “the classification is the same and the field of search is the same and there is no clear indication of separate future classification and field of search, no reasons exist for dividing among related inventions.” Preliminarily, Applicants note that the targets and sequences presently claimed are all related to the same gene, CD81.

Surprisingly, however, the Office states that “a search of more than one (1) of the antisense target region sequences recited in claim 1 presents an undue burden on the Patent and Trademark Office *due to the complex nature of the search and corresponding examination of more than one (1) of the claimed antisense sequences*. In view of the foregoing, one (1) antisense sequence is considered to be a reasonable number of sequences for examination.” (emphasis added). The Office fails, however, to explain why the search or the examination of the claimed subject matter is “complex”.

Applicants direct the Office’s attention to MPEP § 802.01 which sets forth guidelines for establishing a “serious burden.” For example, “a serious burden may be *prima facie* shown if the examiner shows by appropriate explanation of separate classification, or separate classification in the art, or a different field of search as defined in MPEP § 808.02.” The Examiner alleges that:

a search of the available sequence databases produces a listing of references disclosing the sequence most similar to the query sequence (target region). This is the ‘place’ where the examiner searches for prior art. The prior art relating to another query sequence (a different target region) will not be found in this ‘place’- a different listing of references must be generated and searched by the examiner. Thus, a different search is shown, and restriction is proper.

(Office Action, pages 3-4). The Office, although appearing to allege that different search terms may be required for each sequence, fails even to allege that the “field of search” for each sequence is different, as required by MPEP § 808.02. It appears that the Office apparently misinterpreted the requirements set forth in MPEP § 808.02. The Office has not made any showing that each sequence has a separate classification. Indeed, had the Examiner classified each of the sequences set forth in claim 1, for example, each would

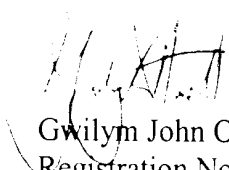
have been classified in the same class and subclass. The Office has also failed to provide any evidence that in the future each sequence will be classified separately. The *field of search* or, in the parlance of the Office, the "place where the examiner searches for prior art", is the same for each region of the target (i.e. CD81), as well as each oligonucleotide directed thereto. As acknowledged by the Examiner, "the antisense compounds . . . each target and modulate the expression of the same gene [CD81] . . ." (Office Action, page 2). The *field of search* is the gene CD81, e.g., SEQ ID NOS: 3, 10, or 11. Each of the target regions represents a subset of SEQ ID NOS: 3, 10, or 11, and each of the antisense compounds targeted to a particular target region is, by definition, targeted to CD81, e.g., SEQ ID NOS: 3, 10, or 11.

The Office appears to assert that just because different search terms may be required to search for the regions/sequences of CD81, that the field of search for each will necessarily differ. Applicants disagree. The field of search is CD81 regions/sequences, not the results of each of the searches.

No amount of undue burden to the Patent Office is presented because the pending claims require searching of the same field. Accordingly, Applicants respectfully request that the Office withdraw the present Restriction Requirement and examine all the pending claims. If this proposal is not satisfactory to the Office, Applicants suggest that an election of species requirement is a more appropriate means of limiting the number of searches. For example, such an election of species requirement may require the election for search of one of the regions set forth in claim 1 and one of the oligonucleotide sequences set forth in claim 3.

The examination of these claims and passage to allowance are respectfully requested. An early Notice of Allowance is therefore earnestly solicited. Applicants invite the Examiner to contact the undersigned at (215) 665-6904 to clarify any unresolved issues raised by this response.

Respectfully submitted,



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